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AUG 2 4 2004

510(k) Summary

As Required by 21 section 807.92 (c)

1- Submitter Name: Sein Electronics Co., Ltd
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5- Contact Person: Won-Ky Kim
6- Date summary prepared: August 5, 2004
7- Official Correspondent: Mansour Consulting LLC
8- Address: 1308 Morningside Park Dr. Alpharetta, GA 30022 USA
9- Phone: 770-777-4146
10- Fax: 678-623-3765
11- Contact Person: Jay Mansour, President
12- Device Trade or Proprietary Name: Full Auto Wrist Digital Blood Pressure Monitor SE-311.
13- Device Common or usual name: Digital Blood Pressure Monitor
14- Device Classification Name: Non Invasive blood pressure measuring system
15- Substantial Equivalency is claimed against the following device:
Full Auto Wrist Digital Blood Pressure Monitor, Model SE-312, manufactured by Sein Electronics Co., Ltd. 510k #K012054

16- Description of the Device:

Full Auto Wrist Digital Blood Pressure Monitor SE-311 is intended to measure systolic and diastolic pressure and pulse rate of adults in a home care environment using wrist cuff and oscillometric method of measurement.

There are no contraindications; the subject device may be employed in the care of normotensive, hypertensive, or hypotensive patents.

The user interface panel of SE-311 has power button, setting button, time button, user button, memory button and liquid crystal display ("LCD") for displaying systolic pressure, diastolic pressure, pulse rate, time, date and user. SE-311 has memory capacity to store the 180 most recent measurement results for four users and the function to transmit the measured data to PC through RS232C cable.

The patient is responsible for applying the cuff, for initiating the measurements sequence by pressuring the "Power" button, and for recording results. The patient cannot alter bleed-down rate.

All system functions are preprogrammed. The user is cautioned in the instruction manual against attempting any programming or other modification.

No special training beyond basic ability to follow instruction is required. Since the products are designed for home use, detailed instructions on avoidance of practices that adversely affect the accuracy of measurements are included in the instruction manual.

17- Intended use of the device: (refer to FDA form attached)

This device is an over the counter device, and its intended use is to measure systolic and diastolic pressure and pulse rate of adults by the individual, in a home care environment, using wrist cuff and oscillometric method of measurement.

18- Safety and Effectiveness of the device:

This device is safe and effective as the predicate device cited above.
This is better expressed in the tabulated comparison (Paragraph 14 below)

14- Summary comparing technological characteristics with predicate device:

Please find below a tabulated comparison supporting that this device is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached. Indeed, this device is **SUBSTANTIALLY EQUIVALENT** to the predicate device. Refer to the explanations/details within the main submission.

FDA file reference number	510k # K012054
TECHNOLOGICAL CHARACTERISTICS	**Comparison result**
Indications for use	Identical
Target population	Identical
Design	Similar
Materials	Identical
Performance	Identical
Sterility	Not Applicable
Biocompatibility	Identical
Mechanical safety	Identical
Chemical safety	Not Applicable
Anatomical sites	Identical
Human factors	Similar
Energy used and/or delivered	Identical
Compatibility with environment and other devices	Identical
Where used	Identical
Standards met	Identical
Electrical safety	Identical
Thermal safety	Identical
Radiation safety	Not Applicable

Refer to the submission for more details.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 4 2004

Sein Electronics Co., Ltd.
c/o Jay Mansour, MSQA, BE, LA, RAC
President
Mansour Consulting, LLC
1308 Morningside Park Drive
Alpharetta, GA 30022

Re: K042138
Trade Name: Full Auto Wrist Digital Blood Pressure Monitor SE-311
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: August 05, 2004
Received: August 09, 2004

Dear Mr. Mansour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D. for BDZ
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K042138

Indications for Use

510(k) Number (if known):

Device Name: Full Auto Wrist Digital Blood Pressure Monitor SE-311

Indications For Use:

This device is an over the counter device, and is indicated for use to measure systolic and diastolic pressure and pulse rate of adults by the individual, in a home care environment, using arm cuff and oscillometric method of measurement.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ✔ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for BDZ

sion Sign-Off)
sion of Cardiovascular Devices

k) Number K042138

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